REMARKS

Claims 1, 5-6, 22-24, and 26-28 are pending in this application. Claims 6, 23, 24, 26, and 27 were withdrawn by the Examiner as directed to a non-elected invention. Claim 1 has been amended, claim 25 has been canceled, and new claim 28 has been added. Support for these amendments and new claim 28 can be found throughout the application as filed, e.g., at page 9, lines 12 to 14.

Rejection Under 35 USC § 112, first paragraph

Claims 1 and 22 have been rejected under 35 U.S.C. § 112, first paragraph as allegedly lacking written description. The Office Action states that:

> The claim(s) contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor(s), at the time the application was filed, had possession of the claimed invention."

Applicants respectfully disagree. However, in the interest of moving the present application toward allowance, applicants have amended claim 1 to recite "said compound being a peptide consisting of amino acid sequence LNRRA (SEQ ID NO:1)." Applicants reserve the right to pursue claim 1, in unamended form, in one or more continuation applications.

A skilled practitioner would have appreciated that the applicants had possession of this compound at the time the application was filed. The complete structure of the claimed compound, i.e., the peptide LNRRA, is described in the specification as SEQ ID NO:1. Similarly, the physical properties, functional characteristics, and method of making such a peptide are described in the application, e.g., at page 9, lines 9 to 19 and at page 17, lines 11 to 23.

Further, applicants have added new claim 28, which recites:

> A compound that modulates the activity of a catalytic antibody, wherein said compound has a specific affinity for a catalytic site of said antibody, is non immunogenic, and is a ligand that binds to a receptor, said compound being a peptide fragment of TNF-alpha that binds to cell receptor p55.

The instant specification describes three such peptide fragments of human TNF-α: LNRRA, IASVY, and LFA. Applicants submit that the species described in the specification are representative of the genus of peptide fragments of TNF-alphas that bind to cell receptor p55. Thus, applicants submit that amended claim 1, dependent claim 22, and new claim 28 satisfy the written description requirement.

Applicants also respectfully point out that catalytic antibodies and their applications were well known at the time of filing, and are described throughout the specification, e.g., at pages 2 to 5 of the present specification. The specification describes at least on page 2 that "natural" catalytic antibodies have DNAse or protease activity. The specification also states that "A catalytic DNA hydrolysis activity was demonstrated in the serum of patients with lupus erythematosus or rheumatoid arthritis (Shuster A M et al, Science (1992) 256: 665-667)." Moreover, at least page 5 of the specification describes that a catalytic antibody recognizes, specifically and not exclusively, two types of molecules, i.e., an antigen or immunogen and a substrate for the chemical reaction catalyzed by the catalytic antibody.

Applicants therefore submit that catalytic antibodies were well known in the art at the time the application was filed, and respectfully point out that it is not necessary for applicants to describe what was known in the art at the time of filing. To that end, the MPEP at 2163.II.A.3(a) states:

> What is conventional or well known to one of ordinary skill in the art need not be disclosed in detail. See *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d at 1384, 231, UPSQ at 94. If a skilled artisan would have understood the inventor to be in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate description requirement is met. See, e.g., *Vas-Cath*, 935 F.2d at 1563, 19 USPQ2d at 1116; *Martin v. Johnson*, 454 F.2d 746, 751, 172 USPQ 391, 395 (CCPA 1972).

Furthermore, that certain examples provided in the specification appear to be prophetic should have no bearing on the Office's determination as to whether the pending claims satisfy the written description requirement. The issue is whether a skilled practitioner would have appreciated, at the time of filing of the application, that the inventors had possession of the claimed invention. It is applicants' position that skilled practitioners, having read applicants'

specification and examples, would have appreciated that applicants had possession of compounds, e.g., that increase the catalytic activity of secreted IgA directed against herpes simplex, antibodies that hydrolyze certain peptide sequences of TNF-α for treating rheumatoid arthritis, antibodies that hydrolyze cocaine to treat drug tolerance phenomenon, antibodies with β-lactamase activity, and antibodies that hydrolyze an allergen to diminish or prevent an allergic reaction. Applicants submit that all of these examples demonstrate that the inventors had possession of the claimed invention. Applicants submit that this is sufficient to satisfy the written description requirement.

Thus, Applicants submit that the written description requirement is satisfied by the amended claims. Reconsideration and withdrawal of this rejection is thus respectfully requested.

Rejection Under 35 USC § 102 / 103

Claims 1, 5, 22, and 25 have been rejected as allegedly anticipated by or obvious over Miller et al. (WO 96/34887). Applicants traverse this rejection with respect to the amended claims for the reasons described below.

As described above, applicants have amended claim 1 to recite "said compound being a peptide consisting of amino acid sequence LNRRA (SEQ ID NO:1)." Miller, on the other hand, describes an antisense peptide which is designed against a particular peptide of TNF-alpha, i.e., LNRRAN. Miller does not teach the composition recited in amended claim 1 and, therefore, the composition of claim 1 is different from the sequence disclosed in Miller. For this reason, the rejection under 35 USC § 102 should be reconsidered and withdrawn.

Miller also does not render the claims obvious. Contrary to the Office's assertion, Miller does not appear to teach a composition that is the amino acid residues 29-34 of TNF-alpha, LNRRAN. Rather, Miller discloses a peptide IGPAVQ, which is the "antisense peptide" of LNRRAN. Such antisense peptides are defined in miller at page 7, lines 24-34, as peptides encoded by nucleotide sequences which are antisense to the nucleotide sequence encoding a target molecule. Miller et al. teaches that such antisense peptides can be useful as antagonists of target molecules, such as TNF-alpha. Miller does not teach, or even suggest, a compound

consisting of the amino acid sequence LNRRA. There is no mention in Miller of any ability of peptide fragments directly derived from TNF-α to have a binding affinity with a catalytic site of a catalytic antibody. There is also no mention in Miller of a need for peptides that would have no immunogenic properties. There is thus no incentive for the skilled person to select the specific peptide LNRRA from TNF-α in order to design a compound capable of interacting with a catalytic antibody that can be involved in enzymatic disorders. There is no motivation in Miller et al. to modify the sequence LNRRAN for use in the methods described therein. No skilled practitioner would have been motivated by Miller to modify any sequence described therein, including the sequence LNRRAN, to arrive at the compounds recited in claim 1 or new claim 28.

For the reasons discussed above, applicants request that the rejection under 35 USC § 102/103 should be reconsidered and withdrawn, and that it not be applied to new claim 28.

Enclosed is check for the Petition for Extension of Time fee. Please apply any other charges or credits to deposit account 06-1050, referencing Attorney Docket No. 16773-002001..

Respectfully submitted,

Date: 10/6/05

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